



19-FEB-1998-0730

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McNEIL CONSUMER P  
FORT WASHING

Individual Safety Report



\*3031836-X-88\*

Page \_\_\_\_\_

A. Patient information				C. Suspect medication(s)	
1. Patient identifier Case 249 In confidence	2. Age at time of event: or 28 yrs Date of birth:	3. Sex (X) female ( ) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 acetaminophen/opiate #2	
B. Adverse event or product problem 1. X Adverse event and/or Product problem (e.g., defects/malfunctions) 2. Outcomes attributed to adverse event (check all that apply) (x) death (unknown) ( ) disability ( ) life-threatening ( ) congenital anomaly (x) hospitalization - initial or prolonged ( ) required intervention to prevent permanent impairment/damage ( ) other: 3. Date of event unknown (mo/day/yr) 4. Date of this report 02/06/98 (mo/day/yr) 5. Describe event or problem Case # 249 received from the 1996 case fatality data. See attached case report form provided by 6. Relevant tests/laboratory data, including dates See attached case report form provided by 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) See attached case report form provided by				2. Dose, frequency & route used #1 unknown dose, po #2	
				3. Therapy dates (if unknown, give duration) from/to for best estimate #1 unknown dates or duration #2	
5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A 8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A				4. Diagnosis for use (indication) #1 toothache and pneumonia #2	
				6. Lot # (if known) #1 Unknown #2	
9. NDC # - for product problems only (if known) - - -				7. Exp. date (if known) #1 Unknown #2	
				10. Concomitant medical products and therapy dates (exclude treatment of event) See attached case report form provided by	
G. All manufacturers					
1. Contact office - name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034				2. Phone number 215-233-7820	
4. Date received by manufacturer (mo/day/yr) 01/30/98				3. Report source (check all that apply) ( ) foreign ( ) study (x) literature ( ) consumer (x) health professional ( ) user facility ( ) company representative ( ) distributor ( ) other:	
6. If IND, protocol #				5. (A) NDA # 17-552 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes	
7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #				8. Adverse event term(s) COMA HYPOTENSION LIVER FAILURE ACIDOSIS RESPIRATORY DIS HEART ARREST DEATH	
9. Mfr. report number 0929811A				E. Initial reporter	
1. Name, address & phone # MD Centers Suite Avenue					
2. Health professional? (X) Yes ( ) No		3. Occupation physician		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk	



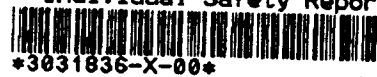
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



19-FEB-1998-0731

Individual Safety Report



\*3031836-X-00\*

**FATALITY: 1996**

**Case Number:** 249

**Age:** 28 yrs

**Substances:** Acetaminophen/opiate

**Chronicity:** Unknown

**Route:** Ingestion

**Reason:** Int unknown

**Pre-Hospital Arrest?** No

This was a 28 year old woman with a history of alcohol and amphetamine abuse who was admitted to a hospital comatose, hypotensive, and in fulminant hepatic failure. Admission laboratory studies revealed AST = 14,000, ALT = 4000, INR = 4, pH = 7.08, and APAP level = 26 mcg/ml. The patient was given NAC, and levophed for hypotension. She required ventilatory support with PEEP for a deteriorating respiratory status secondary to ARDS. The patient expired within 72 hours of admission after a cardiac arrest.

Later history revealed that the patient was being treated with an opiate-APAP combination for a toothache and pneumonia. No coroner's report was available. Death most likely was secondary to acetaminophen-induced liver failure.